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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,126	03/14/2001	Torben Halkier	3631-0108P	6308

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,126	HALKIER ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24,28, in part, drawn to a method for *in vivo* down regulation of osteoprotegerin ligand activity in an animal comprising administering a protein.

Group II, claim(s) 1-21,25-28, in part, drawn to a method for *in vivo* down regulation of osteoprotegerin ligand activity in an animal comprising administering nucleic acid.

Group III, claim(s) 29, drawn to a method for treating osteoporosis comprising administering a protein.

Group IV, claim(s) 29, drawn to a method for treating osteoporosis comprising administering nucleic acid.

Group V, claim(s) 30-32, drawn to the OPGL analogue.

Group VI, claim(s) 33-44, 47, 48, drawn to nucleic acid, vector, cell and the method of preparing the cell.

Group VII, claim(s) 1-19, 45, in part, drawn to a method for in vivo down regulation of osteoprotegerin ligand activity in an animal comprising administering transformed cells or virus.

Group VIII, claim(s) 46, drawn to a pharmaceutical composition comprising nucleic acid.

Group IX, claim(s) 49,50 drawn to a method for identifying OPGL polypeptides which comprises preparing, testing and isolating members of OPGL polypeptides which induce antibody production.

Group X, claim(s) 49, 51,52, drawn to a method for identifying OPGL nucleic acid fragments which comprises preparing, testing and isolating members of OPGL nucleic acid which induce antibody production.

Group XI, claim(s) 53, 54, drawn to the use of OPGL or a substance thereof comprising an adjuvant for down regulating OPGL activity in an animal or treating osteoporosis.

Group XII, claim(s) 55, 56, drawn to the use of OPGL analogue comprising an adjuvant for down regulating OPGL activity in an animal or treating osteoporosis.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 54 does not constitute a special technical feature as it does not define a contribution over the prior art. Claim 54 is drawn to the use of OPGL comprising an adjuvant for the treatment, prophylaxis or amelioration of osteoporosis or other conditions characterized by excessive bone resorption. The instant claim is anticipated by Boyle US Patent No. 5,843,678. Boyle teaches osteoprotegerin binding protein used in the treatment of bone diseases such as osteoporosis (abstract; column 2, lines 45-55; column 3, lines 16-18 and column 7, lines 50-60). As the invention does not make a contribution over the prior art, unity of invention is lacking and restriction is appropriate.

The special technical feature of Group I is a method for *in vivo* down regulation of osteoprotegerin ligand activity in an animal comprising administering a protein. The special technical feature of Group II is a method for *in vivo* down regulation of osteoprotegerin ligand activity in an animal comprising administering nucleic acid. The special technical feature of Group III is a method for treating osteoporosis comprising administering a protein. The special technical feature of Group IV is a method for treating osteoporosis comprising administering nucleic acid. The special technical

feature of Group V is the OPGL analogue. The special technical feature of Group VI is nucleic acid, vector, cell and method of preparing the cell. The special technical feature of Group VII is a method for in vivo down regulation of osteoprotegerin ligand activity in an animal comprising administering transformed cells or virus. The special technical feature of Group VIII is a pharmaceutical composition comprising nucleic acid. The special technical feature of Group IX is a method of identifying OPGL polypeptides. The special technical feature of Group X is a method of identifying OPGL nucleotides. The special technical feature of Group XI is the use of OPGL and an adjuvant. The special technical feature of Group XII is the use of OPGL analogue and an adjuvant.

Groups I, II, III, IV, VII, IX, X are directed to methods which recite structurally and functionally distinct elements, are not required one for the other and/or achieve different goals and thus do not share a common special technical feature. The products of Groups V, VI, VIII, XI and XII are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. The products are distinct both physically and functionally, are not required one for the other, can be prepared by processes which are materially different, isolated from diverse sources and/or used in different methods.

Furthermore, if Applicant elects Groups I, III or V:

Applicant must elect a single OPGL polypeptide (SEQ ID NO:) AND Applicant must also elect a single OPGL structure. The Groups recite numerous forms of OPGL polypeptides, each of which are structurally unique and require its own search.

Further, if Applicant elects Groups II, IV, VI, VII, VIII, X or XII:

Applicant must elect a single nucleic acid (SEQ ID NO:). The Groups recite numerous forms of OPGL nucleic acids, each of which are structurally unique and require its own search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
RMD
June 27, 2002

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600